



June 18, 2007

U.S. Securities and Exchange Commission Division of Corporation Finance Office of International Corporate Finance 100 F Street N.E., Mail Stop 3628

Washington, DC 20549 Phone: 202 551 3450

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SUPPL

Re:

Diamyd Medical AB File No. 82-34956

Documents Furnished Pursuant to Rule 12g3-2(b)

### Ladies and Gentlemen:

We hereby submit, pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934, as Amended, the enclosed press release of Diamyd Medical AB:

Press Release dated as of June 18, 2007: "DIAMYD DIABETES STUDY INVALIDATED"

Kindly acknowledge receipt of the enclosed material by stamping the copy of this letter and returning it in the self-addressed stamped envelope provided.

Very truly yours,

Michael A. Christini

**Enclosure** 

Nils Fredrik-Kaiser cc:

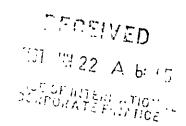
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### DIAMYD DIABETES STUDY INVALIDATED

Press Release, Stockholm, Sweden, June 18, 2007 – Diamyd Medical AB (www.omxgroup.com, ticker: DIAM B; www.otcqx.com, ticker DMYDY)

Diamyd Medical reported today that a Phase II study with Diamyd<sup>®</sup> to improve HbA1c levels in 160 LADA patients (Latent Autoimmune Diabetes in Adults) has been invalidated. The invalidation of the trial is due to inconclusive and contradictory results from the study in combination with critical observations made during a formal independent audit of the handling of the Investigational Product (Diamyd<sup>®</sup> and placebo). Based on detailed reviews and recommendations by auditors and scientific advisors, the Company has decided to invalidate the study.

Moreover, it has recently been established that the correct endpoint for measuring beta cell function is insulin secretion after a standardized meal. The current LADA trial had HbA1c, a long term average blood sugar parameter, as clinical endpoint. As LADA patients are insulin resistant they receive blood glucose reducing agents (insulin sensitizers) and their HbA1c values will be treated to near normal. Therefore the additional HbA1c effect from Diamyd<sup>®</sup> that is given to treat autoimmunity may be less pronounced in well treated patients. The choice of HbA1c as endpoint may have added to the inability to draw conclusions from the study.

Upon review of preliminary data after the initial un-blinding, significant inconsistencies in the efficacy data alerted the investigators to carefully evaluate the clinical design and management of the trial. These investigations uncovered several possible parameters that could influence the efficacy data. An independent audit of the central pharmacy that was handling the Investigational Product (Diamyd® and placebo) concluded that it was impossible to guarantee absolute identity of the contents of each vial of the Investigational Product administered to the patients.

Anders Essen-Moller, CEO of Diamyd Medical, says: "We are really disappointed that we are unable to draw any useful conclusions from this study. There is a chance that a mix up between Diamyd<sup>®</sup> and placebo has been made at some point during the study. A review of the raw data indicated that the results from the first 80 patients enrolled were substantially different from the second group of 80 patients enrolled. During the audit of the pharmacy, it was discovered that the color coding of the Diamyd<sup>®</sup> and placebo vials had been made at two different occasions and that these corresponded to the first and second cohorts of 80 patients. Was the drug mixed up? We do not know. Could there be a mix up at some other times in the study? Yes it is possible, but that is not certain. At the audit of the central pharmacy, where the study product and the placebo were prepared, several findings were made. Of those, two observations were critical and concerned the identification marking of drug vials containing both Diamyd<sup>®</sup> and placebo. The conclusion was that there was a significant risk that the products had been mislabelled. Accordingly, based on the information from the audit, we see at this time no other alternative than to invalidate the study. In view of the different results between the two groups of 80 patients and the findings during the audit, it would be wrong to draw any conclusion regarding efficacy from the study. We will



however continue to look for answers to some remaining unanswered questions and report if any additional light is shed over the outcome of this study."

Essen-Moller continues: "The invalidation of this study will not impact on the timeline for the Diamyd® vaccine to reach the market for treatment of type 1 diabetes. For that reason, we also believe that this invalidated LADA study will not impact our ongoing partnering discussions."

"The discrepancy in the data coupled with the findings during the audit of the study forces us to realize that any preliminary conclusion made from the study amounts only to speculation," says Professor Carl-David Agardh, Malmo University Hospital, Malmo Sweden, Principal Investigator for the study. "Importantly, however, no serious adverse events related to either Diamyd® or placebo were noted in the trial."

"Since the results are not reliable, my recommendation is to repeat the trial, which I think is the only solution," says the auditor Bengt Agrell, Senior Adviser, CEO, GCP Consulting AB, Uppsala; member of Swedish Academy of Pharmaceutical Sciences and Swedish Association for Research Quality Assurance (SARQA), previously appointed *Pharmaceutical Inspector* with Medical Products Agency, Uppsala, Sweden (GCP inspections of phase I-IV trials).

# **Type 1 Diabetes**

In August 2006, the Company reported a successful phase II study with Diamyd<sup>®</sup>. In this study, 70 recent onset type 1 diabetes patients were treated with two injections of Diamyd<sup>®</sup> or placebo and the Diamyd group showed significantly higher meal stimulated insulin levels than the placebo group. In addition, Diamyd<sup>®</sup>-treated patients showed a clear favorable immune response.

# **Partnering**

Diamyd Medical is conducting partnering discussions with Big Pharma. In the situation where a partner's main interest is type 1 diabetes, the Company has reason to believe that the invalidation of the LADA-study will not in a major way adversely affect this partner's interest in Diamyd<sup>®</sup>.

### **Development Timeline**

Diamyd Medical plans to initiate phase III studies for the type 1 diabetes indication in about six months. "We believe that once the phase III studies are ongoing for type 1 diabetes, a small additional study in LADA patients may suffice to broaden the application for LADA-patients," says Essen-Möller. "For that reason we will continue to work on both the type 1 diabetes and the LADA indications."

#### Financing

Diamyd continues to hold partnering discussions. "Should partnering discussions not result in an agreement by the time that our phase III studies gets near the patient recruitment stage, we intend to offer our shareholders the opportunity to continue to build value in Diamyd Medical and participate in the financing of these studies," says Essen-Moller.

## **About Diamyd Medical**

Diamyd Medical is a life science company developing treatments for diabetes and its complications. The company's furthest developed project is the GAD-based drug Diamyd<sup>®</sup> for

autoimmune diabetes. Diamyd<sup>®</sup> has demonstrated significant and positive results in phase II clinical trials in both type 1 and autoimmune type 2 diabetes patients (LADA) in Sweden.

GAD65, a major autoantigen in autoimmune diabetes, is the active substance in Diamyd<sup>®</sup>. GAD65 is also an enzyme that converts the excitatory neurotransmitter glutamate to the inhibitory transmitter GABA. In this context GAD may have an important role not only in diabetes, but also in several central nervous system-related diseases. Diamyd Medical has an exclusive worldwide license from the University of California at Los Angeles regarding the therapeutic use of the GAD65 gene.

Diamyd Medical has sublicensed its UCLA GAD65 Composition of Matter license to Neurologix, Inc. in Fort Lee, New Jersey for treatment of Parkinson's disease with an AAV-vector.

Other projects comprise drug development within gene therapy using the exclusively licensed and patent protected Nerve Targeted Drug Delivery System (NTDDS). The company's lead gene therapy projects include using Enkephalin and GAD for chronic pain, e.g., diabetes pain or cancer pain. All projects in this field are currently in preclinical phases.

Diamyd Medical has offices in Stockholm (Sweden) and in Pittsburgh (USA). The Diamyd Medical share is quoted on the Stockholm Nordic Exchange in Sweden (ticker symbol: DIAM B) and on the OTCQX-list in the US (ticker symbol: DMYDY) administered by the Pink Sheets and the Bank of New York (PAL). Further information is available at www.diamyd.com.

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